

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Copying Claims

New claims 80-94 were copied from U.S.S.N. 11/187,411 and correspond to allowed claims 52-54, 58, 60, 68, 69, 73, 98, 100, 101, 103, 105, and 106 of U.S.S.N. 11/187,411. Support for new claims 80-92 is provided below and references the paragraph number in the published application. U.S.S.N. 11/187,411 is assigned to Biocompatibles UK, Limited. A Notice of Allowance was mailed in U.S.S.N. 11/187,411 on March 29, 2010.

New claims 95-97 were copied from U.S.S.N. 11/489,895 and correspond to pending claims 1, 9, and 19. U.S.S.N. 11/489,895 is assigned to Biocompatibles UK, Limited.

Support for copied claims 80-94

| <u>Claim</u> | <u>Specification</u> |
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| 80. A therapeutic implant, for use in brachytherapy | paragraph 0002, which discloses that the application relates to implantable brachytherapy devices |
| a single metallic radioactive seed that includes radioactive material contained within a metallic housing | paragraphs 0039, 0088, and 0094 (disclose that the seeds described therein can be made of a biocompatible substance, such as titanium or stainless steel) |
| polymeric material which encapsulates the metallic housing of the single seed | paragraph 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably through out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of conventional seeds), and paragraphs 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands) 0084 (uniform coating and partial coating) 0085 (coating material), and 0092 and |

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| <p>wherein an outer surface of the encapsulating polymeric material defines one or more ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation and wherein a thickness of the encapsulating polymeric material varies such that the thickness is greater where there is one of the one or more ribs than where there is not a rib</p> | <p>Figure 2 (enveloping a strand with a sleeve formed from a polymeric material)</p> <p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a "stepped portion" where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105)</p> <p>Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably. Further, the disclosure that the hollow tube can have any length encompasses rings, bands, or ribs of polymer. Discrete section can be formed by molding or adhering the polymer to the seed or strand (paragraph 0100). Paragraph 0118 describes ridges</p> |
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| 81. The implant of claim 80, wherein the one or more ribs are made from the polymeric material that encapsulates the metallic material of the single radioactive seed | Figure 3D (discloses ribs or fins formed from a polymeric material) and paragraphs 0103 and 0105 (disclose rings or bands of a polymeric radiopaque marker) |
| 82. The implant of claim 81, wherein the polymeric material is bioabsorbable | paragraph 0094 (discloses that the polymeric material can be biodegradable) |
| 83. The implant of claim 80, wherein the one or more ribs are defined by a shape of a mold that is used to encapsulate the seed | Paragraph 0092 and Figure 3D. Paragraph 0092 discloses that the polymeric material can be in the form of a sleeve which envelops the seed or strand. Figure 3D shows a seed or strand having one or more ribs. The polymeric material containing the ribs can be a sleeve as described in paragraph 0092 |
| 84. The implant of claim 80, wherein the one or more ribs form one or more rings or a helix about the radial circumference of the metallic housing of the radioactive seed | paragraphs 0103, 0105, and 0120 as discussed above with respect to claim 80 |
| 85. The implant of claim 80, wherein the thickness of the encapsulating polymeric material that encapsulates the metallic housing of the single radioactive seed is at least 0.002 inches. | paragraphs 0087-0089 |
| 86. The implant of claim 80, wherein at least one of the one or more ribs extends at least 0.002 inches beyond portions of the encapsulating polymeric material where there is not a rib. | paragraphs 0087-0089 |
| 87. The implant of claim 80, wherein the metallic housing of the single radioactive seed includes first and second longitudinal ends, and wherein the one or more ribs are located between the longitudinal ends of the metallic housing of the single radioactive seed | paragraph 0039, 0103, 0105, and 0120, for the reasons discussed above with respect to claim 80 |
| 88. The implant of claim 80, wherein the metallic housing of the single radioactive seed | paragraphs 0005, 0039, and 0094 |

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| has a substantially smooth outer surface, without any protrusions, that is completely encapsulated by the polymeric material. | |
| 89. The implant of claim 80, wherein the polymeric material is bioadhesive | paragraphs 0107-0112 and Figure 6 (discloses polyimide hairs or setae, which are bioadhesive) |
| 90. The implant of claim 80, wherein the biomaterial is bio-adherent | paragraphs 0107-0112 and Figure 6 (discloses polyimide hairs or setae, which are bioadhesive) |
| 91. A therapeutic implant, for use in brachytherapy, comprising a single radioactive seed that includes radioactive material contained within a metallic housing having a substantially smooth outer surface; and a polymeric material molded to completely encapsulate the metallic housing of the single radioactive seed; wherein an outer surface of the encapsulating polymeric material includes a plurality of ribs having a substantially squared profile formed by a stepped portion extending between a pair of sidewalls to reduce a tendency of the implant to migrate and rotate within a patient's body after implantation; and wherein the ribs are defined by variations in a thickness of the encapsulating polymeric material, not by an outer surface of the underlying metallic housing. | paragraphs 0002, 0039, 0103, 0105, 0119, Figure 2, and Figure 3D as discussed above with respect to claim 80 |
| 92. The implant of claim 91, wherein the polymeric material is bioadhesive | paragraphs 0107-0112, which discloses polyimide hairs or setae, which are bioadhesive |
| 93. The implant of claim 91, wherein the biomaterial is bio-adherent | paragraphs 0107-0112, which discloses polyimide hairs or setae, which are bioadhesive |
| 94. The implant of claim 91, wherein a thickness of the encapsulating polymeric | Figure 3D |

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| material varies such that the thickness is greater where there is a the rib than where there is not a rib | |
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Support for copies claims 95-97

| <u>Claims</u> | <u>Specification</u> |
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| 95. An anchor mechanism to reduce a tendency for a structure to migrate or rotate after implantation of the structure into a patient, where the structure is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising: | paragraphs 0017 (strand), 0033 and 0039 (seed containing a radioactive material, i.e., radioactive source), and 0105 (polymeric radiopaque marker) |
| a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve | paragraphs 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands), 0084 (uniform coating and partial coating), 0085 (coating material), 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material), and Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard- |

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| | sized brachytherapy strand. As discussed above strands and seeds are used interchangeably |
| one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation, | Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a "stepped portion" where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105) |
| wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion. | Figure 3D |
| 96. A therapeutic implant, for use in brachytherapy, comprising: a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, and an anchor mechanism comprising: | paragraphs 0017 (strand), 0033 and 0039 (seed containing a radioactive material, i.e., radioactive source), and 0105 (polymeric radiopaque marker) |

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| <p>a sleeve to fit around the structure, the sleeve having a bore that extends an entire longitudinal length of the sleeve, and through which the structure fits, such that a portion of the structure extends out from each longitudinal end of the sleeve</p> | <p>paragraphs 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands), 0084 (uniform coating and partial coating), 0085 (coating material), 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material), and Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably</p> |
| <p>one or more protrusions extending from an outer surface of the sleeve along at least a portion of the longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions to receive surrounding patient tissue upon implantation of the structure into a patient, to thereby reduce a tendency for the structure to migrate and rotate after implantation,</p> | <p>Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a "stepped portion" where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque</p> |

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| | markers include polymeric radiopaque markers, as disclosed at paragraph 0105) |
| wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion. | Figure 3D |
| 97. A method for using a therapeutic implant, for use in brachytherapy comprising: providing a structure that is one or more of a radioactive source, a spacer, a strand, or a radiopaque marker, the anchor mechanism comprising: | paragraphs 0017 (strand), 0033 and 0039 (seed containing a radioactive material, i.e., radioactive source), and 0105 (polymeric radiopaque marker) and paragraph 0018 (administration by needle). |
| fitting a sleeve to fit around the structure such that a portion of the structure extends out from each longitudinal end of the sleeve | paragraphs 0048 (discloses polymers can be used to form, or to coat, strands; seed and strand are used interchangeably though out the specification, see for example paragraphs 0054 and 0065, and paragraph 0089, which discloses diameters and lengths of convention seeds), and 0048 (polymers can be used to coat devices), 0083 (film coating of seeds or strands), 0084 (uniform coating and partial coating), 0085 (coating material), 0092 and Figure 2 (enveloping a strand with a sleeve formed from a polymeric material), and Paragraph 0092 discloses that hollow tube 18 can have any wall thickness or length suitable for wholly or partially enveloping a standard-sized brachytherapy strand. As discussed above strands and seeds are used interchangeably |
| wherein the sleeve includes one or more protrusions extending from an outer surface of the sleeve along at least a portion of the | Figure 3D (discloses a seed or strand having at least one rib having a substantially square profile formed by a stepped portion extending |

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| longitudinal length of the sleeve, the one or more protrusions having a substantially squared profile formed by at least a pair of sidewalls spaced along the longitudinal length to form at least one of a space within the one protrusion and space between the protrusions | between a pair of sidewalls), paragraph 0119 (discloses the use of a polymeric material to form ring-shaped structures around the seed), Figure 3F (discloses circumferential axial indentations which are for cutting or breaking, but which clearly result in a "rib-like" effect, i.e., squared off areas of polymer that are thicker than adjoining areas), paragraph 0090 (discloses one or more cavities or pores to increase the surface area of the strand exposed to the target tissue – this can be construed as structures with a "stepped portion" where portions of the polymer coating are thicker than other portions), and paragraph 0103 (discloses that the radiopaque marker can take the form of two bands or rings placed at two locations along the outer surface of the cylindrical strand or seed; suitable radiopaque markers include polymeric radiopaque markers, as disclosed at paragraph 0105) |
| loading the structure, with the sleeve around the structure, into a hollow needle; and using the hollow needle to implant the structure, with the sleeve around the structure, into patient tissue; | Paragraph 0018 |
| wherein the patient tissue is caught in at the at least one space upon implantation of the structure, with the sleeve around the structure, to thereby reduce a tendency for the structure to migrate and rotate at implantation | Paragraphs 0018, 0101, 0118, 0119, and 0121 |
| wherein a thickness of the sleeve varies such that the thickness is greater where there is one of the one or more protrusions than where there is not a protrusion. | Figure 3D |

Claims 36-46 and 48-97 are pending upon entry of this amendment. Favorable consideration is requested. Applicants contend that claims 36-46 and 48-97 are novel and non-

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obvious over the art cited by the Examiner for the reasons provided in the Amendment and Response filed on January 28, 2010.

Interference with U.S.S.N. 11/187,411 and U.S.S.N. 11/489,895

As discussed with SPE Hartley, Applicant believes the present application should be placed in an interference with U.S.S.N. 11/187,411 and U.S.S.N. 11/489,895 to Lamoureux *et al.* To facilitate declaration of an interference, claims 80-97 have been added.

A Suggestion for Interference between the present application and with U.S.S.N. 11/187,411 and U.S.S.N. 11/489,895 to Lamoureux is enclosed.

Allowance of claims 36-46 and 48-79, as amended, and new claims 80-97 is respectfully solicited.

Respectfully submitted,

/Michael J. Terapane, Ph.D., J.D./
Michael J. Terapane, Ph.D., J.D.
Reg. No. 57,633

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PABST PATENT GROUP LLP
1545 Peachtree St., Suite 320
Atlanta, Georgia 30309
(404) 879-2155
(404) 879-2160 (Facsimile)